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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,652	01/23/2004	Robert Edward Aucr	14487	8546

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BECKMAN COULTER INC.  
C/O SHELDON MAK ROSE & ANDERSON  
100 East Corson Street  
Third Floor  
PASADENA, CA 91103-3842

EXAMINER
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VALENTIN, JUAN D

ART UNIT	PAPER NUMBER
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2877

MAIL DATE	DELIVERY MODE
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10/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/763,652

Applicant(s)

AUER ET AL.

Examiner

Juan D. Valentin II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-11, 17-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 7-13, 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (USPN '796, hereinafter Martin) in view of Hansen et al. (USPN '412, hereinafter Hansen).

#### **Claims 1, 8-11, 19**

Martin in conjunction with Fig. 1, discloses a system for measuring the irradiance of a fluorescently labeled particle 20,22 consisting essentially of a cytometric flow chamber 16 having a flow path for passage of the fluorescently labeled particle 20,22, a plurality of excitation light sources (claim 11, laser, col. 4, lines 4-5) 10,12, each emitting a beam of light 18,50 incident on the cytometric flow chamber 16, a plurality of scatter detectors (claim 8) 32,34 in optical communication with the flow path of the cytometric flow chamber 16, each configured to detect light 36 from only one of the plurality of excitation light sources 10,12 and arranged so as to detect scattered light 36 from the fluorescently labeled particle 20 as it passes through the flow path of the cytometric flow chamber 16 (col. 2, lines 43-56, col. 2, lines 62-65, col. 3, line 61-col. 4, line 8).

Martin further discloses a plurality of triggers (gate signal generators 37,38), each of the plurality of triggers being connected to a separate one of the plurality of scatter detectors 32,34

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that trigger (generate) a signal when scattered light 36 incident on one of the scatter detectors 32. Applicant has argued that Martin fails to teach a system consisting essentially of “a plurality of triggers, each of the plurality of triggers being connected to a separate one of the plurality of scatter detectors”. Applicant kindly disagrees with applicant’s assertion, in that it can be seen in Fig. 1 of Martin that each trigger (Gate Signal Generators 37, 38) are each connected to a separate scatter detector 32,34, therefore reading on the claimed limitation. Applicant argues that the Gate Signal Gen 38 is also connected to Gate Signal Gen 1, therefore Gate Signal Gen 1 is also therefore connected scatter detector 34. Examiner disagrees with applicant’s interpretation of Martin. Applicant has not claimed that the plurality of triggers could not be connected to each other or anything else for that matter. The specification is not clear as to whether the trigger can be connected to each other, so for the purposes of searching and prior art, it is the position of the Office that Martin teaches said claimed limitation.

It is noted that any substantial scattering signal received from the light scatter detectors 32,34 and sent to the gate signal generator is deemed to exceed a predetermined threshold value whether it be any signal above zero or some other optimal scatter light detection value which triggers the gate signal generator to send signals to the gate signal processor (col. 2, line 62-col. 3, line 13, col. 4, line 21-col. 5, line 13).

Martin discloses the newly added subject matter “wherein the at least one integrator is controlled only by a separate one of the plurality of triggers in response to scattered light incident on of the scatter detectors”. It can be clearly seen from Fig. 1 of Martin that once particle 20 passes within light beam 18, then clearly this limitation is satisfied because once light 18 scatters off of particle 20, light scatter detector 1 will receive this scattered light, and send a signal to

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trigger (gate signal generator 1) which will then send a signal to the integrator (1 gated signal processor) which clearly reads on this newly added limitation. Therefore one trigger only controls the integrator at that particular point in the measurement process of Martin.

Martin discloses at least one fluorescence detector (claim 9) 24,26 to receive the emissions collected by the collection optics and generate an output, the at least one fluorescence detector 24,26 being configured to respond only to a discrete number of wavelength bands (col. 2, lines 50-61, col. 4, lines 4-20 & 40-55), and at least one integrator 38,40 connected to the trigger (gate signal generator) and the at least one fluorescence detector 24,26, for recording the output of the at least one fluorescence detector 24,26 in response to a signal from the trigger 37,38 (col. 4, line 32-col. 5, line 14).

Martin substantially discloses the claimed invention, but fails to disclose collection optics and spectral filters in optical communication with the flow path of the cytometric flow chamber to collect emissions (photomultiplier) from the fluorescently labeled particle and photodiodes (photo sensors) to detect scattered light. While using collection optics and spectral filters to couple light of specific wavelengths into detectors (photomultiplier tubes) and using photodiodes to detect scattered light is well known to someone of ordinary skill in the art at the time of the claimed invention, Hansen shows that it is known to provide collection optics to couple fluorescent light emitted by particles into photomultiplier tubes as well as photosensors to detect scattered light (claims 8-10, Fig. 1, refs. 107, 111, 112, 113, col. 4, lines 32-66) for an fluorescence detecting flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of Martin with the fluorescence collection optics of

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Hansen for the purposes of providing efficient couple of fluorescence emitted by particles under test within the flow cytometry chamber.

Regarding the newly claimed subject matter of claim 13, Martin clearly discloses the structure of the system of claim 13, and while applicant has claimed that the spacing and order of the light beams does not need be predetermined, that fact of the matter is that it still can be and said limitation places no further structural limitations on the claimed subject matter.

### **Claims 2, 3**

Martin discloses the use of distinct light source and detector pairs for the purposes of illuminating and detecting separate wavelengths of light, as well as emitted fluorescents which are wavelength specific depending on the particular dye(s) used (col. 2, lines 50-61, col. 4, lines 4-20). It would have been obvious to someone of ordinary skill in the art at the time of the claimed invention was made to add at least one more light source and detector pair for the purposes of providing detection of an additional/different fluorescent dye (fluorochrome), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

### **Claim 7**

Martin substantially discloses the claimed invention, but fails to disclose wherein the at least two excitation light sources are focused to overlap in the flow path of the flow chamber. Hansen shows that it is known to provide two excitation light sources are focused to overlap in the flow path of the flow chamber (Fig. 1) for an fluorescence detecting flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of

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Martin with the overlapping excitation beams of Hansen for the purposes of providing cell sensing response of fluorescence to specific types of illumination (Hansen, col. 4, lines 11-15).

2. Claims 4, 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Hansen and further in view of Pinkel (USPN '619).

**Claims 4, 6**

Martin substantially discloses the claimed invention but fails to disclose the use of band pass/spectral filters in combination with the scatter detectors. Pinkel shows that it is known to provide the use of band pass/spectral filters in combination with the scatter detectors (Fig. 1, refs. 18 & 20, col. 2, lines 34-40) for a fluorescence detecting flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of Martin with the spectral filters of Pinkel for the purposes of providing spectral filtering of collected scattered light in a flow cytometry system.

3. Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Hansen and further in view of Kramer (USPN '634 B2).

**Claim 5**

Martin substantially discloses the claimed invention but fails to disclose wherein the three excitation light sources are positioned about an excitation light axis, a fiber optic bundle is configured around the excitation light axis, the fiber optic bundle containing three sets of optical fibers, and each set of optical fibers is optically coupled to a different one of the three scatter detectors. Kramer shows that it is known to provide wherein the three excitation light sources

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are positioned about an excitation light axis, a fiber optic bundle is configured around the excitation light axis, the fiber optic bundle containing three sets of optical fibers, and each set of optical fibers is optically coupled to a different one of the three scatter detectors (col. 7, line 60-col. 8, line 59) for a fluorescence detecting flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of Martin with the fiber bundle light detection configuration of Kramer for the purposes of providing a relatively small area of respective light-collecting ends by using the optical fibers collection configuration, and further the fibers collect relatively little stray laser light reflecting from various surfaces (e.g. the faces of the optical flow cell, Kramer, col. 11, lines 51-56).

4. Claims 17-18 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Hansen and further in view of Hoffman (USPN '038).

#### **Claims 17-18**

The methods are substantially suggested by the functions set forth with regards to the apparatus claims 1 & 8-11 as rejected above in view of Martin in view of Hansen except fails to show assigning any detected fluorescence to dyes known to be excited by the first and second excitation light sources respectively and the number of fluorescence detectors equal to the number of maximum number of dyes stimulated by either first or second light sources and using a multi-pass band pass filter to filter the fluorescence emitted to each of the fluorescence detectors. Applicant argues that Hoffman does not disclose the use of the one fluorescence detector and therefore can not dynamically assign the fluorescent dyes (see page 15, lines 1-25 of Remarks section dated 07/23/2007). However, in claim 17, applicant has not claimed a single



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fluorescence detector nor "dynamically" assigning fluorescent labels (emphasis added).

Hoffman shows that it is known to provide assigning any detected fluorescence to dyes known to be excited by the first and second excitation light sources respectively and the number of fluorescence detectors equal to the number of maximum number of dyes stimulated by either first or second light sources and using a multi-pass band pass filter (optical-subsystem 16, col. 5, lines 12-21) to filter select wavelengths of light to each of the fluorescence detectors respectively (col. 4, line 39-col. 5, line 28) for an multi-laser flow cytometry system. It would have been obvious to combine the device of Hansen with the fluorochrome (fluorescent dye) detection and assignment and fluorescent dye stimulation of Hoffman for the purposes of providing detecting and classifying of multiple fluorescent dyes.

Hoffman clearly shows the strong excitation of 3 fluorescent dyes using the single blue laser L72 in Fig. 1 (col. 5, lines 12-28) which shows the number of fluorescence detectors (3) equaling the number of fluorescence dyes strongly excited by the second light source as claimed by applicant and further using a wavelength filtering optical subsystem (i.e. multiband pass filtering system). Therefore the combination of Martin in view of Hoffman is deemed proper and the rejection is maintained.

***Allowable Subject Matter***

5. Claims 16, 19-20 are allowed over prior art of record.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding the allowability of claims 16, and 19-20 please refer to page 14, line 16-page 15, line 25 of applicant's remarks dated 07/23/2007. Prior art fails to teach or suggest the dynamic assignment of fluorescent labels in combination with the other limitations of claims 16 and 19 respectively.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

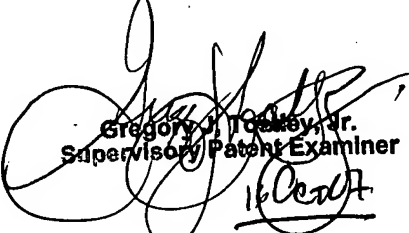
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juan D. Valentin II whose telephone number is (571) 272-2433. The examiner can normally be reached on Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on (571) 272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JDVII/  
Juan D Valentin II  
2007-10-15  
JDV

  
Gregory J. Tuckey, Jr.  
Supervisory Patent Examiner  
16 Oct 07